REMARKS

Status of the Patent Claims

Claims 1-15 are pending. The claims have been amended to return them to their original form. The pending claims 1-15 are the original claims 1-15 of U.S. Patent No. 6,365,574, on which this reissue application is based.

Reissue Declaration

Claims 1-7 were rejected as being based on a defective reissue declaration.

The Office Action took the position that the terms "non-hygroscopic" and "less hygroscopic than azithromycin monohydrate" have different meanings in the art. Without acquiescence with the Office Action's position, applicants note that the term "non-hygroscopic" is no longer in the pending claims, so this issue is now moot. However, the Applicants continue to maintain, as explained in the previous Amendment, that the meaning of the phrase "non-hygroscopic" has the same meaning as "less hygroscopic than azithromycin monohydrate," as found by the Board of Patent Appeals and Interferences in the interference proceedings related to U.S. Patent No. 6,365,574 (the parent for which the instant 10/816,376 reissue application was filed). The Office Action's position on the "meanings" of "non-hygroscopic" and "less hygroscopic than azithromycin monohydrate" is inconsistent with the finding of the Board of Patent Appeals and Interferences.

The Office Action states that the reissue declaration is defective because it fails to identify at least one error which is relied upon to support the reissue application. Because the error under 35 U.S.C. 251 relied upon in support of the reissue application can be affected by the final version of the claims as found by the Examiner to be otherwise allowable, the Applicants request that requirement for Supplemental Reissue Declaration be held in abeyance until the claims are indicated as being otherwise allowable. Applicants also note that in the prosecution of the reissue application, an error in the chemical formula of azithromycin in column 1, lines 18-33, of U.S. Patent No. 6,365,574 was corrected via the Amendment filed on June 26, 2009.

Written description

Claims 1 and 4 were rejected under 35 U.S.C. §112, first paragraph, for lack of written description because, in the Examiner's view, the specification indicates that the inventors possessed only an ethanolate having a water content from about 2% to about 4%.

The Applicants respectfully traverse this rejection. One of ordinary skill in the art reading the specification would clearly understand that the specification teaches that the invention is not just an ethanolate of azithromycin with a particular water content but rather an ethanolate of azithromycin having an ethanol content of about 1.5% to about 3%, no matter what the water content. While the present specification refers to some embodiments of the invention that contain about 2% to 4% water (see column 1, lines 64-65; column 2, line 26; and Table 1), there are far more references simply to an "ethanolate," without qualification as to water content. See column 1, line 10; column 1, line 61; column 1, line 67; column 2, lines 7-8; column 2, line 32; column 3, lines 16-17; column 3, line 55; and column 4, line 6. In particular, the original claim 1 in U.S. Application Serial No. 09/451,738, which issued as U.S. Patent No. 6,365,574, is directed to an "ethanolate of azithromycin having an ethanolate content of about 1.5% to about 3%" without any qualification as to the water content. Applicants submit that the applicants had possession of the ethanolate of azithromycin having ethanolate content of about 1.5% to about 3%.

The Applicants respectfully request that this rejection be withdrawn.

The Applicants hereby make a Conditional Petition for any relief available to correct any defect seen in connection with the filing of this paper. The Commissioner is authorized to charge Kenyon & Kenyon LLP's Deposit Account No. 11-0600 for the Petition fee and any other fees required to effect this Conditional Petition.

Respectfully submitted,

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/King L. Wong/

King L. Wong
Reg. No. 37,500

KENYON & KENYON LLP
One Broadway
New York, NY 10004
(212) 425-7200 (telephone)
(212) 425-5288 (facsimile)
Customer No. 26646